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CERTIFIED TRUE COPY

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FILED

APR 12 2005

BOARD OF PHARMACY

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE SUSPENSION
OR REVOCATION OF THE PERMIT OF

EZRX, L.L.C.

TO OPERATE A PHARMACY IN THE
STATE OF NEW JERSEY

:
: Administrative Action
:
: **PROVISIONAL ORDER**
: **OF DISCIPLINE**
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:
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:
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This matter was opened to the New Jersey State Board of Pharmacy upon receipt of information which the Board has reviewed and on which the following preliminary findings of fact and conclusions of law are made;

FINDINGS OF FACT

1. Respondent is a pharmacy in the State of New Jersey and has been a retail permit holder at all times relevant hereto.

2. On November 29, 2004 respondent's DEA Certificate of Registration BE8488783 was revoked by the Drug Enforcement Administration. (Order attached hereto and made a part of this Order.) Specifically, respondent continued to dispense controlled

dangerous substances without ensuring prescriptions were issued for a legitimate medical purpose pursuant to a valid patient-physician relationship.

3. The following disciplinary action was ordered; revocation of the DEA permit of EZRX, LLC and the denial of any pending applications for renewal of such registration.

CONCLUSIONS OF LAW

The above disciplinary action by a federal agency provides grounds for the revocation of the permit to operate a pharmacy in the State of New Jersey pursuant to N.J.S.A. 45:1-21(g) in that respondent's authority to engage in the dispensing of controlled dangerous substances has been revoked by the Drug Enforcement Administration. (Order attached hereto and made a part of this Order.)

ACCORDINGLY, IT IS on this 23rd day of March, 2005,

ORDERED that:

1. Respondent's permit to operate a pharmacy in the State of New Jersey be and hereby is revoked.

2. The within Order shall be subject to finalization by the Board at 5:00 p.m. on the 30th business day following entry hereof unless respondent requests a modification or dismissal of the above stated Findings of Fact or Conclusions of law by:

(a) Submitting a written request for modification or dismissal to, Joanne Boyer, Executive Director, State Board of Pharmacy, 124 Halsey Street, Sixth Floor, Newark, New Jersey 07101.

(b) Setting forth in writing any and all reasons why said findings and conclusions should be modified or dismissed.

(c) Submitting any and all documents or other written evidence supporting respondent's request for consideration and reasons therefor.

3. Any submissions will be reviewed by the Board, and the Board will thereafter determine whether further proceedings are necessary. If no material discrepancies are raised through the submission by respondent during the thirty-day period, or if the Board is not persuaded that submitted materials merit further consideration or mitigation of the penalties set forth herein, a Final Order of Discipline will be entered.

4. In the event that respondent's submissions establish a need for further proceedings, including, but not limited to, an evidentiary hearing, respondent shall be notified with regard thereto. In the event an evidentiary hearing is ordered, the preliminary findings of fact and conclusions of law contained herein shall serve as notice of the factual and legal allegations in such proceeding. However, the Board shall not be limited to the sanctions herein and may recoup costs to the State.

NEW JERSEY STATE BOARD OF PHARMACY

By: Pamela Allen R.P.
Pamela Allen, R.P.
President

2004, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on October 22, 2004. The views of the Commission are contained in USITC Publication 3732 (October 2004), entitled Polyvinyl Alcohol from Taiwan: Investigation No. 731-TA-1088 (Preliminary).

By order of the Commission.

Issued: October 25, 2004.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 04-24205 Filed 10-28-04; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[EOIR No. 149]

Executive Office for Immigration Review; Notice Extending Period To File Motions To Reopen Under the *Barahona-Gomez v. Ashcroft* Settlement

AGENCY: Executive Office for Immigration Review ("EOIR"), Justice.
ACTION: Notice.

SUMMARY: This notice is to inform all parties that the motion to reopen period as defined in section (II)(B)(4) of the settlement agreement in *Barahona-Gomez v. Ashcroft*, 243 F. Supp. 2d 1029 (N.D. Cal. 2002), was extended to March 20, 2005. The full settlement agreement can be found at 243 F. Supp. 2d 1029 (N.D. Cal. 2002), and also is reproduced on the EOIR Web site at <http://www.usdoj.gov/eoir>. The settlement agreement initially provided that the motion to reopen period was for eighteen (18) months from the date the Advisory Statement was published in the Federal Register. The Advisory Statement providing notice of the settlement was published in the Federal Register on March 20, 2003. See 68 FR 13727. The motion to reopen period was to close on September 20, 2004. Under section (II)(B)(4) of the settlement agreement, if any eligible class member filed a motion to reopen proceedings under the settlement agreement within six months prior to September 20, 2004, the motion to reopen period is extended for an additional 180 days. This notice acknowledges that the deadline date was extended to March 20, 2005.

DATES: The deadline for filing motions to reopen under the settlement agreement was extended to March 20, 2005.

FOR FURTHER INFORMATION CONTACT: MaryBeth Keller, General Counsel,

Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041, telephone (703) 305-0470.

Dated: October 15, 2004.

Kevin D. Rooney,

Director, Executive Office for Immigration Review.

[FR Doc. 04-24208 Filed 10-28-04; 8:45 am]

BILLING CODE 4410-30-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to 21 CFR 1301.33(a), this is notice that on May 25, 2004, Cambrex North Brunswick Inc., Technology Centre of New Jersey, 661 Highway One, North Brunswick, New Jersey 08902, made application by renewal and on June 11, 2004 by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed:

Drug	Schedule
N-Ethylamphetamine (1475)	I
Tetrahydrocannabinols (7370)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxymphetamine (7400)	I
4-Methoxyamphetamine (7411)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Morphine (9300)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (ODLR) and must be filed no later than December 28, 2004.

Dated: October 1, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 04-24154 Filed 10-28-04; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

EZR, LLC Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to EZRX, LLC (EZRX) of Union, New Jersey. EZRX was notified of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BE8488783, as a retail pharmacy, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that its continued registration would be inconsistent with the public interest. EZRX was further notified that its DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension alleged in sum, that EZRX was engaged in illegally dispensing controlled substances as part of a scheme in which controlled substances were dispensed by EZRX based on Internet orders placed by customers and approved by associated physicians, based solely on their review of Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued "in the usual course of professional treatment" and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.

According to the investigative file on May 26, 2004, the Order to Show Cause and Immediate Suspension of Registration was personally served by Special Agents and Diversion Investigators of the DEA at EZRX's registered premises in Union, New Jersey. More than thirty days have passed since the Order to Show Cause

and Immediate Suspension of Registration was served on EZRX and DEA has not received a request for hearing or any other reply from EZRX or anyone purporting to represent it in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to EZRX, and (2) no request for hearing having been received, concludes that EZRX is deemed to have waived its hearing right. See David W. Linder, 67 FR 12,579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds EZRX is currently registered with DEA as a retail pharmacy under DEA Registration, BE8488783 to dispense Schedule II through V Controlled Substances. That registration expires on August 31, 2006. The owners of EZRX are Frank C. Hernandez and his wife, Amada Hernandez.

In 2003, the DEA Miami Field Division initiated regulatory investigations of C&H Wholesale, Inc. (C&H) and Lifeline Pharmacy, Inc. (Lifeline). C&H was registered with DEA as a distributor of Schedule II through V controlled substances and Lifeline was registered as a retail pharmacy of the same substances. Both companies are owned by Mr. and Mrs. Hernandez and the registered premises they occupy are physically connected and share floor space with the Hernandez' non-drug businesses.

During the regulatory examination of C&H, it was discovered that C&H was distributing controlled substances almost exclusively to South Florida pharmacies, including Lifeline, which were filling Internet controlled substance prescriptions. The majority of distributions were for Schedule III and IV controlled substance weight loss medications including, but not limited to substantial quantities of phentermine, phendimetrazine tartrate, Dexedrine and tennate.

On October 10, 2003, as a result of investigative findings that C&H and Lifeline were facilitating and dispensing controlled substances by virtue of prescriptions issued not for legitimate medical purposes and not in the usual course of professional medical practice, the then-Acting Deputy Administrator issued orders to show cause to C&H and Lifeline and immediately suspended their registrations on grounds that the

posed an immediate threat to the public health and safety.

Subsequent investigation by Miami DEA investigators revealed that on August 21, 2003, the same day a federal search warrant was being executed on Lifeline's Florida premises, Mr. Hernandez filed a new application for registration on behalf of EZRX, as a retail pharmacy in New Jersey. That application was inadvertently routinely processed in New Jersey while the Miami investigation was still in process and it was approved on September 9, 2003. Later, in the course of document review, DEA Miami investigators found paperwork indicating Mr. and Mrs. Hernandez were the owners of EZRX and that two Florida employees, Mr. Hernandez' nephew and wife, were also key employees of the New Jersey retail pharmacy.

On November 6, 2003, DEA Miami investigators made an undercover buy from a Florida-based website. Using a fictitious name and an undercover Internet e-mail account and computer, investigators placed an order for Bontril, a Schedule IV controlled substance weight loss medication. After filling out a medical questionnaire on the website and sending a money order to an affiliated company, E.V.A. Global, Inc., a package was received at the undercover address via Federal Express. It was shipped by EZRX on November 11, 2003, from its registered address and contained 89 Bontril SR 105mg capsules. The prescription label indicated it had been dispensed by EZRX and the issuing physician was an individual, later identified as a DEA registrant, who had prescribed controlled substances during similar undercover purchases made through Lifeline. There was no contact between the prescribing physician and the undercover investigator, other than transmission of the Internet questionnaire.

Another physician involved with Internet prescribing through E.V.A. Global, Inc. was interviewed by investigators and described the process. He would access a web site provided him by E.V.A. Global, Inc., where customers' medical questionnaires would be posted. The physician would access the questionnaires one at a time, review the questionnaire and either approve or deny the prescription request. He did not have the ability to suggest an alternative drug or an alternate amount and there was never any contact between the physician and either the "patient" or the dispensing pharmacy.

It was determined that from September through November 2003, "

EZRX ordered in excess of 300,000 dosage units of Schedule III and IV controlled substances, including the controlled substances commonly sold through websites affiliated with E.V.A. Global, Inc., to include phentermine, Ionamin, Meridia, Didrex, phendimetrazine tartrate and Ambien.

The Controlled Substances Act (CSA) establishes a "closed system" of distribution that regulates the movement of controlled substance prescription medications from importation or manufacture through their delivery to the ultimate user patient via the dispensing, administering or prescribing, pursuant to the lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a).

Prescriptions issued not in the "usual course of professional treatment" are not "prescriptions" for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's controlled substances provisions.

In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court held that, "Implicit in the registration of a physician is the understanding that he is authorized only to act 'as a physician'." *Id.*, at 141. In *Moore* the court implicitly approved a jury instruction that acting "as a physician" is acting "in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.*, at 138-139; see, *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986).

Responsible professional organizations have issued guidance in this area. The American Medical Association's guidance for physicians on the appropriate use of the Internet in prescribing medication (H-120.949 Guidance for Physicians on Internet Prescribing) states:

"Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:

i. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying

conditions and/or contraindications to the treatment recommended/provided;

ii. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);

iii. As appropriate, follow up with the patient to assess the therapeutic outcome;

iv. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and

v. Include the electronic prescription information as part of the patient medical record."

In April 2000, the Federation of State Medical Boards adopted Model Guidelines for the Appropriate use of the Internet in Medical Practice, which states, in pertinent part, that:

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

The CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's "corresponding responsibility" regarding the proper dispensing of controlled substances is explicitly described in 21 CFR 1306.04(a). It provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

In an April 21, 2001, policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, *inter alia*, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship required that the patient has a medical complaint, a medical history be taken, a physical examination performed, and some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed. The policy

statement specifically explained that the completion of "a questionnaire that is then review by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship * * *". *Id.*, at 21,182-21,183.

Rogue Internet Pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory and incomplete online questionnaire or perfunctory telephone "consult" with a doctor, who usually has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. The Food and Drug Administration (FDA) considers the questionnaire, in lieu of face-to-face interaction, to be a practice that undermines safeguards of direct medical supervision and amounts to substandard medical care. See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (<http://fda.gov/oc/buyonline/default.htm>).

The National Association of Boards of Pharmacy considers internet pharmacies to be suspect if:

They dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

See, National Association of Boards of Pharmacy, VIIPS Program, Most Frequently Asked Questions (<http://www.nabp.net/viips/consumer/faq.asp>).

Rogue Internet pharmacies often use persons with limited or no knowledge of medications and standard pharmacy practices to fill prescriptions, do not advertise the availability of pharmacists for medication consultation, and focus on select medications, usually lifestyle, obesity and pain medications. Rogue Internet pharmacies generally do not protect the integrity of original faxed prescriptions by requiring that they be received directly from the prescriber (not the patient) and do not verify the authenticity of suspect prescriptions.

When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially

serious health risks to patients. Rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice. The FDA has stated:

We know that adverse events are under-reported and we know from history that tolerating the sale of unproven, fraudulent, or adulterated drugs results in harm to the public health. It is reasonable to expect that the illegal sales of drugs over the Internet and the number of resulting injuries will increase as sales on the Internet grow. Without clear and effective law enforcement, violators will have no reason to stop their illegal practices. Unless we begin to act now, unlawful conduct and the resulting harm to consumers most likely will increase.

See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (<http://fda.gov/oc/buyonline/default.htm>).

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

- (1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable state, federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to a determination of whether EZRX's continued registration remains consistent with the public interest.

With regard to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that EZRX has been the subject of a state disciplinary proceeding, nor is there

evidence demonstrating that its state pharmacy license or state controlled substance authority are currently restricted in any form. Nevertheless, state licensure is a necessary, but not sufficient condition for registration, and therefore, this factor is not dispositive. See e.g., *Wesley G. Harline, M.D.*, 65 FR 5,665-01 (2000); *James C. Lajevic, D.M.D.*, 64 FR 55,962 (1999).

With regard to factors two and four, the Deputy Administrator finds that the primary conduct at issue in this proceeding (i.e., the unlawful dispensing of controlled substance prescriptions for use by Internet customers) relates to both EZRX's and its owners' experience in dispensing controlled substances, as well as its compliance with applicable state, federal, or local laws relating to controlled substances. DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. See *Plaza Pharmacy*, 53 FR 36,910 (1988).

A DEA registration authorizes a physician to prescribe or dispense controlled substances only within the usual course of his or her professional practice. For a prescription to have been issued within the course of a practitioner's professional practice, it must have been written for a legitimate medical purpose within the context of a valid physician-patient relationship. See *Mark Wade, M.D.*, 69 FR 7,018 (2004), 51,600 (1998). Legally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription. See *Floyd A. Santner, M.D.*, 55 FR 37,581 (1990).

Factors two and four are relevant to EZRX's dispensing of Internet prescribed controlled substances. The Deputy Administrator concludes from a review of the record that the physicians issuing these prescriptions did not establish valid physician-patient relationships with Internet customers to whom they prescribed controlled substances. DEA has previously found that prescriptions issued through a pharmacy Internet Web site are not considered as having been issued in the usual course of medical practice, in violation of 21 CFR 1306.04 and has revoked the DEA registrations of several physicians for participating in Internet prescribing schemes similar to or identical to that of EZRX. See, *Marvin Gibbs, Jr., M.D.*, 69 FR 11,658 (2004); *Mark Wade, M.D.*, supra, 69 FR 7,018; *Ernesto A. Cantu, M.D.*, 69 FR 7,104-02

(2004); *Rick Joe Nelson, M.D.*, 66 FR 30,752 (2001).

Similarly, in the past few years, DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill their corresponding responsibility in Internet prescribing operations, similar to those of EZRX and its principals and their affiliated companies. See *Prescriptiononline.com*, 69 FR 5,583 (2004); *Pill Box Pharmacy* (surrendered DEA registration as part of owner's and pharmacy's guilty plea to 21 U.S.C. 841(a)(1) violation); *Friendly Pharmacy* (pharmacist pled guilty and owner convicted at trial, of violating 21 U.S.C. 841(a). Indeed, C&H and Lifeline, the predecessor Internet pharmacy entities owned by EZRX's principals, were both subjects of orders to show cause with immediate suspensions and both companies surrendered their DEA Certificates of Registration.

In the instant case, physicians associated with the Internet operation authorized prescriptions for controlled substances without the benefit of face-to-face physician-patient contact, physical exam or medical test. There is no information in the investigative file demonstrating that the issuing physicians even took the time to corroborate responses to questionnaires that were submitted by EZRX's customers. Here, it is clear that the issuance of controlled substance prescriptions to persons whom the prescribing physician has not established a valid physician-patient relationship is a radical departure from the normal course of professional practice and that EZRX knowingly participated in this scheme.

With regard to factor three, applicant's conviction record under federal or state laws relating to the dispensing of controlled substances, the record does not reflect that EZRX or its principals have been convicted of a felony related to controlled substances.

Regarding factor five, such other conduct which may threaten the public health or safety, the Deputy Administrator finds this factor relevant to EZRX's continued dispensing to Internet customers after issuance of policy statements designed to assist licensed practitioners and pharmacists in the proper prescribing and dispensing of dangerous controlled drugs.

Factor five is also relevant to EZRX's continued Internet prescribing after C&H and Lifeline, both owned by the principals of EZRX, were served with Orders to Show Cause and for Immediate Suspensions in October 2003. These entities sought an order in

United States District Court seeking to restrain DEA from imposing the immediate suspensions of their registrations. After the District Court held hearings to make a threshold determination that DEA had some basis to back up its allegations regarding the Internet prescribing activities of C&H and Lifeline, the Court upheld the immediate suspensions by DEA, finding "there is not a substantial likelihood that C&H and Lifeline will prevail on the merits." It further stated, "the danger of the public obtaining controlled substances outweighs the threatened injury to C&H and Lifeline. Granting the preliminary injunction would affect the public interest, again putting the public in danger of obtaining controlled substances." See *C&H Wholesale, Inc. and Lifeline Pharmacy, Inc.*, CIV. 03-61910 (S.D. Fla., October 23, 2003). Nevertheless after the District Court's Order, EZRX continued this practice and dispensed the controlled substance ordered over the Internet by undercover agents on November 6, 2003.

Similarly, factor five is relevant to Mr. Hernandez' timing in applying for EZRX's DEA registration on August 21, 2003. This is the date a federal search warrant was executed on Lifeline, his Florida pharmacy and further suggests the New Jersey operation was established by Mr. Hernandez to continue Internet dispensing as a back up to his Florida operations.

The Deputy Administrator has previously expressed her deep concern about the increased risk of diversion which accompanies Internet controlled substance transactions. Given the nascent practice of cyber-distribution of controlled drugs to faceless individuals, where interaction between individuals is limited to information on a computer screen or credit card, it is virtually impossible to insure that these highly addictive, and sometimes dangerous products will reach the intended recipient, and if so, whether the person purchasing these products has an actual need for them. The ramifications of obtaining dangerous and highly addictive drugs with the ease of logging on to a computer and the use of a credit card are disturbing and immense, particularly when one considers the growing problem of the abuse of prescription drugs in the United States. See, *Mark Wade, M.D.*, supra, 69 FR 7,018.

The Deputy Administrator has also previously found that in a 2001 report, the National Clearinghouse for Alcohol and Drug Information estimated that 4 million Americans ages 12 and older had acknowledged misusing

prescription drugs. That accounts for 2% to 4% of the populations—a rate of abuse that has quadrupled since 1980. Prescription drug abuse—typically of painkillers, sedatives and mood-altering drugs—accounts for one-third of all illicit drug use in the United States. See Mark Wade, M.D., *supra*, 69 FR 7,018.

The Deputy Administrator finds that with respect to Internet transactions involving controlled substances, the horrific untold stories of drug abuse, addiction and treatment are the unintended, but foreseeable consequence of providing highly addictive drugs to the public without oversight. The closed system of distribution, brought about by the enactment of the Controlled Substances Act, is completely compromised when individuals can easily acquire controlled substances without regard to age or health status. Such lack of oversight describes EZRX, its principals, their associated companies and affiliated physician's practice of issuing prescriptions for and distributing controlled substances to indistinct Internet customers. Such conduct contributes to the abuse of controlled substances by EZRX's customers and is relevant under factor five and further supports revocation of its DEA Certificate of Registration.

It appears that EZRX and its principals, motivated purely by profit and in pursuit of financial gain, have demonstrated a cavalier disregard for controlled substance laws and regulations and a disturbing indifference to the health and safety of customers who purchased dangerous drugs through the Internet. Such demonstrated lack of character and adherence to the responsibilities inherent in a DEA registration show in no uncertain terms that EZRX's continued registration with DEA would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BE8488783, previously issued to EZRX, LLC, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effective November 29, 2004.

Dated: September 29, 2004.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 04-24235 Filed 10-28-04; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-55,382]

Eclipsys Corporation, Santa Rosa, California; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of September 27, 2004, a petitioner requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance, applicable to workers of the subject firm. The Department's determination notice was signed on August 31, 2004. The Notice was published in the Federal Register on September 23, 2004 (69 FR 57093).

The Department reviewed the request for reconsideration and has determined that the original investigation requires further investigation. Therefore, the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 20th day of October, 2004.

Linda G. Poole,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4-2908 Filed 10-29-04; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-55,596]

Interdynamics, Inc., Brooklyn, NY; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 13, 2004 in response to petition filed by a company official on behalf of workers at Interdynamics, Inc., Brooklyn, New York.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 13th day of October, 2004.

Richard Church,
Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4-2910 Filed 10-28-04; 8:45 am]

BILLING CODE 4510-30-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-55,622]

KAMCO Plastics, Inc., Galesburg, IL; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on September 16, 2004 in response to a worker petition filed on behalf of workers at Kamco Plastics, Inc., Galesburg, Illinois.

The petition regarding the investigation has been deemed invalid. In order to establish a valid worker group, there must be at least three full-time workers employed at some point during the period under investigation. Workers of the group subject to this investigation did not meet the threshold of employment. Consequently the investigation has been terminated.

Signed at Washington, DC, this 15th day of October 2004.

Richard Church,
Certifying Officer, Division of Trade Adjustment Assistance.

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DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-55,504]

PPC Insulators Knoxville, TN; Notice of Revised Determination on Reconsideration of Alternative Trade Adjustment Assistance

By letter dated September 30, 2004, the Tennessee AFL-CIO Technical Assistance Center requested administrative reconsideration regarding Alternative Trade Adjustment Assistance (ATAA). The negative determination was signed on September 15, 2004 and published in the Federal Register on October 8, 2004 (69 FR 60427).

The workers of PPC Insulators, Knoxville, Tennessee were certified eligible to apply for Trade Adjustment